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NOA 9-21-90

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☒ This application has been examined ☐ Responsive to communication filed on 1/25/90 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~0~~ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-10, 11-30 are pending in the application.
   Of the above, claims 11-30 are withdrawn from consideration.
2. ☒ Claims 23-26 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-10 are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-30 have been ~~are~~ subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 6-88)

1. The deposit requirement under §112 has been obviated by the required deposit of HB-8483.

2. The §112 rejection is withdrawn with respect to claims 4, 5, 9 and 10. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited to the hybridomas and associated anti-My-10 antibodies used to generate the data of the disclosure. See MPEP 706.03(n) and 706.03(z). Applicant's argument on page 6 of Paper No. 10 has been considered, but does not overcome this rejection. Applicant has not enabled the isolation and production of the broadly claimed monoclonal antibodies. One with skill in the art would have no reasonable expectation of developing monoclonal antibodies with the desired specificity characteristics, because of the inherent unpredictability of monoclonal antibody production techniques, no matter how well those techniques are described. It is suggested that the applicant narrow the claims to the particular species of monoclonal antibodies isolated and characterized in order to obviate this rejection.

3. The §112, second paragraph rejection is withdrawn in view of the amended claim language.

4. The §102 (a) rejection is withdrawn in view of the declaration filed by Dr. Civin (Paper No. 11).

5. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by AS (Civin, 1982) and AT (Civin, 1982). These two abstracts teach the MY-10 antigen, monoclonal antibodies identifying it and use of these monoclonal antibodies in differentiating hematopoietic cells. Applicant argues that these references do not provide the impetus necessary to select the antibodies of the instant claims. However, it appears that the prior art monoclonal antibodies of references R and T read directly on the claims. It is suggested that the applicant narrow the claims to the particular species

enabled by the specification and distinguish the monoclonal antibodies of the claims from those of the prior art to obviate this rejection.

6. The rejection over the Bolger and Nadler references is withdrawn.

7. The rejection of claims 1-10 under §102 (e) based on B (Trowbridge 4,582,797), A (Dupont 4,710,457), C (Kung 4,624,925), D (Kung 4,364,932), E (Kung 4,364,937), or AB (Kung 4,381,295) is withdrawn.

8. Claims 1-10 are rejected under 35 U.S.C. 103 as being unpatentable over Nadler in view of the known availability of leukemic cell lines like KG-1 or KG-1a (AS, AT, AR2, and the specification page 5). Nadler (p.188) teaches:

> . . .the production and characterization of monoclonal antibodies; . . .the characterization of subpopulations of immune cells expressing unique antigens; . . .leukemias and lymphomas utilizing both lineage and differentiation associated antigens; and . . .the clinical, diagnostic and therapeutic utility of these antibodies.

Applicant's argument that the Nadler reference applies only to leukemic cells has been considered, but is not persuasive in view of the citation above regarding characterization of subpopulations of immune cells. It is well-known in the art, as evidenced by Nadler that differentiation antigens are often abnormally expressed on transformed cells. Nadler provides the motivation for developing monoclonal antibodies to these differentiation antigens. Nadler does not teach the particular KG-1a cell line used in the specification. The Civin references and the specification teach the known relevance and public availability of the KG-1a hematopoietic cell line used to make the products of the instant claims. One with ordinary skill in the art would have been motivated to use the techniques of Nadler to make the hybridomas and monoclonal antibodies as broadly claimed in claims 1-3, 6, and 7 from the known KG-1a cell line for the purposes set forth by Nadler. Applicant's filing of factual evidence distinguishing the claimed products from those of the prior art on the basis of unexpected

result (eg. unexpectedly high affinity for the antigen or unexpected specificity) of claims 4-5 and 9-10 obviate the rejection of these claims.

9. THIS ACTION IS MADE **FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

10. A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Thomas M. Cunningham, Ph.D whose telephone number is (703) ~~557-8871~~ 557-5264. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 557-3920.

Cunningham

3/16/90

MARGARET MOSKOWITZ
SUPERVISORY
PATENT EXAMINER
ART UNIT 186